

REMARKS

The Office Action of April 2, 2009, has been carefully studied. Claims 1, 3-6, 8, 11, 12 and 19-27 currently appear in this application. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration and formal allowance of the claims.

Claim Amendments

The claims have been amended to recite "magnetostatic field" rather than "magnetic field." It is clear from the working examples in the specification that one skilled in the art would understand that "magnetic field" is intended to mean a magnetic field which does not change with time, which type of magnetic field is commonly referred to as a "magnetostatic field."

Support for new claims 25-27 can be found in the specification as filed at page 13, line 8 through page 14, line 4, and the figures.

Art Rejections

Claims 1, 3, 4, 11, 12, 19-21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohr et al., US 5,050,293 in light of

support from three entries in Wikipedia, Electric Field, Dielectric Heating, and Magnetic Field.

This rejection is respectfully traversed.

A magnetostatic field is one in which the magnetic field does not change over time. The method claimed herein recites that the formulation is stored under a magnetostatic field, which means that the formulation is stored under a magnetic field that is constant, that is, does not change over time. This constant magnetic field stabilizes the proteins in solution.

In contrast thereto, Bohr discloses a method for changing the functionality of the three-dimensional structure of a chain molecule by applying energy from a high frequency force to a fluid system containing such chain molecules with respect to parameters involving wavelength, amplitude and duration which will initiate a change in the molecular structure. To effect these changes in three-dimensional molecular structures, Bohr applies electromagnetic radiation such as microwaves, which radiation changes with time. The electromagnetic field used in Bohr is clearly different from the magnetostatic field used in the presently claimed invention.

Bohr changes a three-dimensional structure of a chain molecule by rotating or vibrating chemical bonds in the molecule by applying an electromagnetic radiation to the molecule. On the other hand, the presently claimed method is to store a recombinant protein solution formulation under a magnetostatic field, that is, to apply a magnetostatic field to protein molecules in order to **stabilize the protein formulation.** This is entirely different from the process disclosed in Bohr, which **changes** the three-dimensional configuration of the molecules. The presently claimed method stabilizes the protein molecules, while the Bohr method actively changes the configuration of the molecules, which can hardly be considered stabilizing the molecules.

It is clear that applying an electromagnetic wave to a chain molecule in Bohr is completely different from storing a protein formulation under a constant magnetostatic field as claimed herein. Bohr applies radiation to change the structure of the molecules, while the presently claimed method subjects the formulations to a magnetostatic field in order to prevent changes in the protein molecules.

Claims 1, 3-6, 11, 12 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohr in further view of Pantanas et al., (JCO, 1991) and Rosse et al., (ASH, Hematology, 2000).

This rejection is respectfully traversed.

The fact that Pantanas and Rosse disclose that recombinant molecules such as EPO have been used as a therapeutic agent has absolutely nothing at all to do with the presently claimed method.

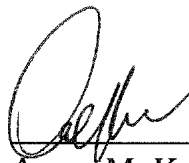
As noted above, Bohr is concerned with **changing** the structure of molecules by subjecting them to electromagnetic radiation. The presently claimed method **stabilizes** protein molecules by treating them with a magnetostatic field, that is, a field that is constant over time, not variable as in Bohr. The magnetic fields used in Bohr originate from microwaves and radio waves, not from magnets, as claimed herein. Therefore, it is respectfully submitted that one skilled in the art could not conceive of the use of a magnet or a magnetostatic field from the disclosure of Bohr. Accordingly, the feature of claims 25-27 are neither taught nor suggested by Bohr, either alone or in combination with any of the cited articles.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Appln. No. 10/524,019
Amd. dated September 24, 2009
Reply to Office Action of April 2, 2009

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: 

Anne M. Kornbau
Registration No. 25,884

AMK:srd
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528

G:\BN\Y\YUAS\Tanikawa1\Pto\2009-09-24Amendment.doc